

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

**JAN VALLEJO, Individually and As
Personal Representative of Steve
Vallejo;**

**Plaintiff,
vs.**

**AMGEN, INC., WYETH, INC., AND
PFIZER, INC.,**

Defendants.

8:14CV50

**MEMORANDUM
AND ORDER**

This matter is before the Court on the Objection to Magistrate Judge Zwart's Order (Filing No. 88) ("Objection"), filed by Plaintiff Jan Vallejo, individually and as personal representative of Steve Vallejo ("Plaintiff"). For the reasons discussed below, the Objection will be overruled.

BACKGROUND

Plaintiff alleges that Steve Vallejo developed myelodysplastic syndrome ("MDS"), as a result of taking the prescription drug Entrancercept, trade named Enbrel ("Enbrel"), ultimately causing his death. (Filing No. 83 at 1.) MDS encompasses a group of related clonal disorders affecting the bone marrow's ability to produce certain cells in healthy amounts. MDS can progress to anemia, leukemia, thrombocytopenia, pancytopenia, and severe marrow failure. Enbrel is an injectable prescription drug that neutralizes certain tumor necrosis factors ("TNFs"), which are proteins made by the body's immune

system. (*Id.*) On February 17, 2014, Plaintiff filed this action against Defendants Amgen Inc., Pfizer Inc., and Wyeth LLC (collectively “Defendants”).¹ (See Filing No. 1.)

On May 5, 2015, Judge Zwart ordered phased discovery, with the first phase devoted to general medical causation, *i.e.*, whether Enbrel can cause MDS (“Phase I”). (Filing No. 55.) After the Parties were unable to comply with Judge Zwart’s order that they submit a joint outline of discovery issues, Judge Zwart held a hearing on December 9, 2015 (“December Hearing”), at which an expert witness testified on behalf of Plaintiff regarding Plaintiff’s discovery needs. (See Filing No. 79.) Judge Zwart ordered the Parties to submit briefs in support of their arguments, and on March 28, 2016, Judge Zwart entered an order (Filing No. 83) (“Order”) setting the bounds of discovery for Phase I.

In the Order, Judge Zwart ruled on Plaintiff’s request for discovery in three areas at issue in this objection: (1) reports concerning Enbrel and related symptomology of MDS; (2) reports concerning non-Enbrel TNF blockers and MDS; and (3) the methods by which Plaintiff may attempt to locate information and documents within Defendants’ possession. (See *id.*)

I. Discoverability of Reports Concerning Related Symptomology

The Parties disputed whether Plaintiff was entitled to studies concerning only MDS or, instead, all symptoms related to MDS. (*Id.* at 6.) Because MDS is not a specific disorder, but rather a spectrum of disorders, Plaintiff argued that she should be

¹ Defendants assert that they are named incorrectly in Plaintiff’s Complaint and, consequently, in the clerk of the court’s captioning of the case. Instead of “Amgen, Inc.,” “Wyeth, Inc.,” and “Pfizer, Inc.,” their actual entity names read “Amgen Inc.,” Pfizer Inc.,” and “Wyeth LLC.” (Filing No. 94 at 1.)

given reports beyond those only mentioning “MDS,” including those referencing a host of medical terms proposed by Plaintiff.

Plaintiff’s proposed search terms conformed to the standardized hierarchy of adverse effect terminology within the MedDRA’s Standardized MedDRA Query (“SMQ”). Each SMQ contains a five-level hierarchy of terms. (Filing No. 83 at 7.) At the lowest, most specific level are Low Level Terms (“LLTs”). In ascending order of breadth, the remaining levels are Preferred Terms (“PTs”), High Level Terms (“HLTs”), High Level Group Terms (“HLGTs”), and System Organ Classes (“SOCs”). (*Id.*)

Judge Zwart noted that “Plaintiff requests reports and studies that mention every SMQ term as it may relate to MDS” and that “the SMQ designates 206 LLTs for MDS.” (*Id.*) Judge Zwart found these terms to be overly broad and ruled that “any discovery of adverse event reports and Enbrel studies be limited to the PT ‘MDS’ and its corresponding fifteen LLTs.”² (*Id.* at 9.)

II. Discoverability of Reports on other TNF blockers

Plaintiff also sought to require Defendants to identify any studies that relate any TNF blocker to MDS or its symptoms; determine if anyone associated with the Defendants supplied any information for those studies; and produce all such information. (*Id.* at 9–10.) Judge Zwart noted in her Order that such information’s relevance was tenuous, given that non-Enbrel TNF blockers operate via different mechanisms and are prescribed for different purposes than Enbrel, and that Plaintiff’s

² Defendants argued that use of the “broad scope” of the SMQ terms sought by Plaintiff was unreasonable and asked Judge Zwart to limit the discovery order to the “narrow scope” of the MDS SMQ. (Filing No. 83 at 8.) Judge Zwart’s review of the SMQ Introductory Guide revealed that, while most SMQs have both narrow and broad scope terms, MDS has only one available scope. Accordingly, Judge Zwart was unable to craft an Order to allow for a narrow scope search of the MDS SMQ. (*Id.* at 9.)

request would require Defendants to “email and search the files of approximately 100,000 employees^[3] for information that may not exist” (*Id.* at 10.)

For these reasons Judge Zwart noted that sustaining Defendants’ objection to the request would be appropriate, but because the case was “languishing,” Judge Zwart ordered a limited set of information to be disclosed. (*Id.*) To wit, the Order required Defendants “to answer or produce discovery regarding studies on the causal relationship, if any, between Enbrel[] and MDS and produce such studies or reports within any Defendant’s custody or control that are not available in the public domain.” (*Id.*)

III. Custodial Information and Documents

To ascertain the existence of relevant information and documents in the Defendants’ possession, Plaintiff sought organizational charts to identify employees responsible for determining whether Enbrel causes or is capable of causing MDS and those working at their direction, the person in charge of compiling adverse events and those working at his or her direction, and the person in charge of maintaining source documents for MDS adverse events. Prior to the December Hearing, Defendants provided Plaintiff the name of Jan Isles, the global safety officer in charge of Enbrel, with the promise to provide additional names as they became aware of them. In her Order, Judge Zwart found that Plaintiff’s request was unreasonably broad given the number of individuals and companies involved with Enbrel’s development and production over its twenty-five year history. (Filing No. 83 at 11–12.) Judge Zwart

³ Defendant Amgen Inc. has approximately 17,900 employees, while Defendant Pfizer Inc. has approximately 78,300. (*Id.* at 10.)

ordered that Plaintiff first depose Ms. Isles and then seek out additional witnesses from Defendants to provide whatever information Ms. Isles could not. (*Id.* at 12.)

Plaintiff filed her Objection to the Order on April 11, 2016. (Filing No. 88.)

STANDARD OF REVIEW

When a party objects to a magistrate judge's order on a nondispositive pretrial matter, a district court may set aside any part of the order shown to be clearly erroneous or contrary to law. Fed. R. Civ. P. 72(a); see 28 U.S.C. § 636(b)(1)(A). “A finding is ‘clearly erroneous’ when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed.” *Chase v. Comm'r*, 926 F.2d 737, 740 (8th Cir. 1991) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948)). “An order is contrary to law if it fails to apply or misapplies relevant statutes, case law, or rules of procedure.” *Haviland v. Catholic Health Initiatives-Iowa, Corp.*, 692 F. Supp. 2d 1040 (S.D. Iowa 2010) (internal quotation marks omitted).

DISCUSSION

Plaintiff specifically objects to (1) Judge Zwart’s denial of Plaintiff’s discovery requests based on considerations of proportionality when, Plaintiff argues, there was a lack of “objective evidence proffered by Defendants;” (2) the weight and credibility, or lack thereof, that Judge Zwart afforded Plaintiff’s expert witness at the December Hearing; (3) Judge Zwart’s limitation of SMQ search terms to those fifteen LLTs corresponding to the PT “MDS”; (4) Judge Zwart’s limitation of the discoverability of information regarding non-Enbrel TNF blockers; and (5) Judge Zwart’s denial of Plaintiff’s request for organizational charts of employees with certain knowledge of

Enbrel. Plaintiff argues that with respect to each portion enumerated within its Objection, the Order is contrary to law and clearly erroneous.

Underlying each portion of Plaintiff's Objection is the argument that Judge Zwart's Order is contrary to law because Defendants introduced insufficient evidence to meet their burden of complying with Plaintiff's discovery requests. In her Order, Judge Zwart stated, "the extent of Defendant's burden has yet to be objectively quantified: Defendants have failed to submit affidavits or sworn information by employees or experts regarding the burden of searching for and providing information or providing any meaningful estimates for the time and cost required by the plaintiff's discovery." (Filing No. 83 at 6.)

Plaintiff cites the advisory notes to Federal Rule of Civil Procedure 26⁴ and *Wagner v. Dryvit Sys., Inc.*, 208 F.R.D. 606 (D. Neb. 2001)⁵ for the proposition that a defendant must introduce evidence of its burden when objecting to a discovery request as overbroad and burdensome. (Filing Nos. 89 at 4–5; 98 at 2.) According to Plaintiff, the Order misapplies these authorities and thus is contrary to law because Judge Zwart found both that Plaintiff's discovery request was overly broad and that Defendants had not introduced sufficient evidence to assist Judge Zwart's discovery determinations.

The authorities on which the Plaintiff relies do not suggest that a magistrate judge loses discretion to fashion a discovery order granting less than what a plaintiff

⁴ "Implicit in the notes is that a producing party must identify the burden and expense associated with Plaintiffs [sic] requests. Without such information, a producing party's arguments are nothing more than boilerplate objections that the requests are not proportional." (Filing No. 89 at 4–5 (citing Fed. R. Civ. P. 26 advisory committee's note to 2015 amendment).)

⁵ "Unless it is obvious from the wording of the request . . . an objection that discovery is overly broad and unduly burdensome must be supported by affidavits or offering evidence revealing the nature of the burden and why the discovery is objectionable." *Wagner v. Dryvit Sys., Inc.*, 208 F.R.D. 606, 610 (D. Neb. 2001).

seeks if a defendant's evidence supporting its objection is unsatisfactory to the judge. Judge Zwart's decision was not made in a vacuum of information regarding the burden Plaintiff's requested discovery would place on Defendants. The advisory committee note cited by Plaintiff states, “[t]he parties and the Magistrate have a collective responsibility to consider the proportionality of all discovery and consider it in resolving discovery disputes.” Fed. R. Civ. P. 26 advisory committee's note to 2015 amendment. That is what occurred here—although Judge Zwart found that neither party had provided “substantial and reasonable guidance” to the Court⁶—and thus, the Order is not contrary to law with respect to any of portion of Plaintiff's Objection.

Plaintiff's argument that Judge Zwart's assessment of burden was clearly erroneous also is without merit. Judge Zwart considered a variety of factors—including the volume of reports Plaintiff's requests would return, the amount of irrelevant information likely to be included, and the number of employees who would have to be questioned⁷—in determining the proportionality of Plaintiff's discovery requests.

Plaintiff also argues that the credibility and weight, or lack thereof, that Judge Zwart afforded Plaintiff's expert witness was contrary to law and clearly erroneous.⁸ For

⁶ Judge Zwart stated that “the attorneys in this case put the onerous responsibility on the court to balance proportionality while failing to provide substantial and reasonable guidance on this key point: In its current state the court is being forced to ‘wade through generalized and conflated arguments of need, burden, and relevance.’” (Filing No. 83 at 5 (quoting Elizabeth D. Laporte & Jonathan M. Redgrave, *A Practical Guide to Achieving Proportionality Under New Federal Rule of Civil Procedure 26*, 9 Fed. Ct. Rev. 20, 29 (2015))).

⁷ (See *id.* at 7–10.)

⁸ Judge Zwart determined that “the expert's testimony was not entirely credible, and her demands are unreasonable” and that the “expert's testimony did not assist the court in determining whether Plaintiff's need for the requested information was proportional to the burden imposed on the defendants in responding to Plaintiff's discovery.” (Filing No. 83 at 4.)

the reasons discussed above, Judge Zwart's Order was not contrary law.⁹ The fact that Defendants did not quantify their burden to the extent Judge Zwart would have liked did not obligate Judge Zwart as a matter of law to accept the Plaintiff's expert witness's testimony in its entirety. Neither has the Plaintiff demonstrated that Judge Zwart's evaluation of the witness's testimony was clearly erroneous. Judge Zwart evaluated the witness's expertise and the content of her testimony and considered it along with the rest of Plaintiff's evidence. That she found the testimony to be of minimal value is not clear error.

Plaintiff next objects to Judge Zwart's limitation of the SMQ search terms to those fifteen LLTs corresponding to the PT "MDS" on the grounds that such a limitation is contrary to Rule 26 and clearly erroneous. For the reasons already discussed, the Order is not contrary to Rule 26. Plaintiff argues that the limitation was clearly erroneous because Judge Zwart limited discovery to something less than what Defendants initially offered to provide, and is inconsistent with "the internationally standardized query for MDS."¹⁰ (Filing No. 89 at 17.) Reaching a decision independent of the arguments of both parties is not clear error. Judge Zwart's Order explained her reasoning as to why the Plaintiff's requested search terms were overly broad, why

⁹ Plaintiff asserts that this portion of the Order is contrary to Federal Rule of Evidence 702. (Filing No. 89 at 7.) Yet Plaintiff admits that Judge Zwart was "not expected . . . to engage in a full F.R.E. 702 type analysis," and that the rule merely provides "some guidance for the evaluation of expert testimony." (*Id.* at 9.) Plaintiff does not explain how Rule 702 obligated Judge Zwart to adopt the entirety of the witness's testimony as a matter of law.

¹⁰ Plaintiff also argues that the Order is clearly erroneous because at the December Hearing Plaintiff performed a demonstrative SMQ search for reports submitted to the FDA to provide an estimate of the number of results its discovery request would return. (Filing No. 89 at 13–15.) The Order noted the relatively large number of results this search returned. (Filing No. 83 at 8.) Plaintiff claims that this search was performed in error and, had it been performed correctly, it would have returned a more reasonable number of results. (Filing No. 89 at 13–15.) This does not constitute clear error *on the part of Judge Zwart*. Judge Zwart considered factors beyond the demonstrative search. That the search may have been performed incorrectly does not leave the Court with "the definite and firm conviction that a mistake has been committed," *Chase*, 926 F.2d at 740.

Defendants' proposal was unhelpful in shaping the Order, and why the Order limited discovery as it did. (See Filing No. 83 at 6–9.) Her reasoning was not clearly erroneous.

Next, Plaintiff objects to Judge Zwart's limitation of the discoverability of information regarding non-Enbrel TNF blockers in two respects: Plaintiff argues that (1) it was clear error to deny Plaintiff's request for information on MDS and non-Enbrel TNF blockers, and (2) the discovery ordered will not lead to the discovery of any reports. (Filing No. 89 at 18.) Judge Zwart's conclusion that “[a] discovery request which requires a party to email and search the files of close to 100,000 employees for information that may not exist and may have no relevancy whatsoever is . . . overbroad” is not clear error. (See Filing No. 83 at 10.) Judge Zwart ordered certain discovery in an attempt to keep the slow-moving discovery of this case progressing, even though she could have sustained Defendants' objection to Plaintiff's discovery request in its entirety. (*Id.*) Although the scope of discovery she ordered may not return what Plaintiff desires, Judge Zwart's action was not clear error.

Finally, Plaintiff objects to Judge Zwart “deny[ing] Plaintiff[] from the discovery of custodial files.” (Filing No. 89 at 20.) Plaintiff admits that this “denial [is] not explicit,” but is rather Plaintiff's inference based on the Order's silence as to such production and certain comments with the Order on the sufficiency of the discovery ordered so far. (*Id.* at 20–21.) Clear error requires a “definite and firm conviction,” *Chase*, 926 F.2d at 740, and cannot be based on Plaintiff's inference of what the Order may or may not imply. The relevant portion of the Order stated that Plaintiff should depose the employee already identified by Defendants and that Defendants may be required to identify further

employees depending on the results of the deposition. (Filing No. 83 at 12.) This does not foreclose Plaintiff's subsequent access to potentially relevant custodial information.

For the reasons stated above, Plaintiff's Objection will be overruled.

Accordingly,

IT IS ORDERED: Plaintiff's Objection to Portions of Magistrates March 28, 2016 Order on Discovery (Filing No. 88) is overruled.

Dated this 20th day of May, 2016.

BY THE COURT:

s/Laurie Smith Camp
Chief United States District Judge